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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,802	04/12/2004	Gabor Pragai	01662/79802	5189

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KENYON & KENYON LLP
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,802	PRAGAI ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-53 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-53 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 04/12/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 16, 17, 22, 42 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10, 16, 17, 42 and 52 recite the limitation "the pH" in line 1. There is insufficient antecedent basis for this limitation in the claim. Their independent claims do not recite "pH" limitation.

Claim 22 is rejected because the language is confusing in view of the phrase "further where" in line 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 13, 15-24, 26-29, 35, 36, 39, 43, 45-47 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemmens et al. US 6,919,087.

Lemmens teaches a pharmaceutical composition comprising amlodipine maleate, and excipients including diluent, binder, disintegrant, and lubricant (abstract;

and column 4, lines 19-43). Excipients such as microcrystalline cellulose, calcium hydrogen phosphate, sodium starch glycolate, magnesium stearate and/or talc are added in the amounts that fall within the claimed ranges (column 5, lines 43-52; column 6, lines 21-42; and examples). The overall pH of the composition is from about 5.5-6.8, and the composition comprises less than 0.5% amlodipine aspartate after 1 month storage at 40°C/75%RH (abstract; stability study of Z#204 in the examples; and claims).

Lemmens is different in the sense that Lemmens teaches the use of magnesium in the composition. However, Lemmens limited the amount of magnesium stearate to as low as less than 0.5% (see example 2) to obtain a stable amlodipine maleate composition useful for the treatment of hypertension or angina (column 6, lines 58-65). Thus, it would have been obvious to one of ordinary skill in the art to, by routine experimentation optimize the amlodipine maleate composition taught by Lemmens to eliminate the use of magnesium stearate to obtain the claimed invention, because Lemmens teaches an amlodipine maleate having the claimed impurity in the same storage condition at one month, because Lemmens teaches a pharmaceutical composition that does not comprise magnesium stearate has been shown to provide good stability against the formation of impurities (column 5, lines 53-56), and because Lemmens teaches the use of magnesium stearate as an optional ingredient (column 6, lines 25-29).

Claims 1-6, 13-30, 35-37, 39, 43-48 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemmens et al. US 6,919,087, in view of Jerzewski et al. US 5,006,344.

Lemmens is relied upon for the reason stated above. Although it would have been obvious Lemmens to one of ordinary skill in the art to, by routine experimentation eliminate the use of magnesium stearate to obtain the claimed invention, however, to be more specific, Jerzewski is cited for the teaching of using other lubricant can improve stability of pharmaceutical formulations (see abstract). Jerzewski teaches using sodium stearyl fumarate or hydrogenated vegetable oil instead of magnesium stearate in a pharmaceutical dosage form, can improve the shelf life and stability of the dosage form (column 1, lines 22-27; and column 2, lines 3-7). Thus, it would have been obvious to one of ordinary skill in the art to modify the composition of Lemmens to use sodium stearyl fumarate instead of magnesium stearate as a lubricant to obtain a stable amlodipine maleate dosage form having the claimed properties, because Jerzewski teaches an increase in shelf life and stability of the dosage form for similar active agent such as an antihypertensive agent without the use of magnesium stearate, and because Lemmens teaches the desirability to obtain a shelf stable composition for an antihypertensive active agent.

Claims 7-12, 31-34, 38, 40-42 and 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemmens et al. US 6,919,087, in view of Jerzewski et al. US 5,006,344 and Marder et al. US 5,674,529.

Lemmens in view of Jerzewski are relied upon for the reasons stated above. The cited references do not teach the claimed lubricant such as hydrogenated castor oil.

Marder teaches lubricant useful in pharmaceutical dosage form includes hydrogenated castor oil, hydrogenated vegetable oil, and salts of stearyl fumarate (column 7, lines 48-51). Thus, it would have been obvious to one of ordinary skill in the art to select hydrogenated castor oil as a lubricant in view of the teaching of Marder, because Marder teaches the equivalency between hydrogenated castor oil, hydrogenated vegetable oil, and salts of stearyl fumarate as a lubricant, because Marder teaches hydrogenated castor oil is a well known lubricating agent in pharmaceutical art, because Jerzewski teaches an increase in shelf life and stability of the dosage form in the use of hydrogenated oil as a lubricant, and because Lemmens teaches the desirability to obtain a shelf stable composition.

Claims 1-5, 13, 15-24, 26-29, 35, 36, 39, 43, 45-47 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jerzewski et al. US 5,006,344, in view of Chakole et al. US 2003/0180354.

Jerzewski teaches a stable composition comprising salt of an anti-hypertension agent, and excipients including lubricant, filler, disintegrant, and binder (column 2, lines 3-49). Excipients such as microcrystalline cellulose, sodium starch glycolate, magnesium stearate and/or talc are added in the amounts that fall within the claimed ranges (column 2, lines 30-69; and examples). Lubricating agent includes hydrogenated vegetable oil and sodium stearyl fumarate (ID).

Jerzewski does not explicitly teach the claimed active agent.

Chakole teaches a stable pharmaceutical composition comprising amlodipine maleate as an anti-hypertension agent, and pharmaceutically acceptable excipients (abstract; paragraphs 0011-0021; and claims). Chakole further teaches the claimed pH, and stability at 40°C/75%RH for one month (examples). Thus, it would have been it would have been obvious to one of ordinary skill in the art to modify the composition of Jerzewski using amlodipine maleate as an anti-hypertension agent in view of the teaching of Chakole, because Chakole teaches amlodipine as anti-hypertension agent that is well known in the art to exhibits better bioavailability and absorbability (paragraphs 0003-0004 and 0027), and because Jerzewski teaches an increase in shelf life and stability of the dosage form for similar active agent such as an antihypertensive agent.

Claims 7-12, 31-34, 38, 40-42 and 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jerzewski et al. US 5,006,344, in view of Chakole et al. and Marder et al. US 5,674,529.

Jerzewski and Chakole are relied upon for the reasons stated above. The cited references do not teach the claimed lubricant such as hydrogenated castor oil.

Marder teaches lubricant useful in pharmaceutical dosage form includes hydrogenated castor oil, hydrogenated vegetable oil, and salts of stearyl fumarate (column 7, lines 48-51). Thus, it would have been obvious to one of ordinary skill in the art to select hydrogenated castor oil as a lubricant in view of the teaching of Marder,

because Marder teaches the equivalency between hydrogenated castor oil, hydrogenated vegetable oil, and salts of stearyl fumarate as a lubricant, because Marder teaches hydrogenated castor oil is a well known lubricating agent in pharmaceutical art, because Jerzewski and Chakole teach a stable dosage form in the use of hydrogenated oil as a lubricant.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Billotte et al. is cited as of interest for the teachings of a stable formulation of amlodipine maleate.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SUSAN TRAN
PRIMARY EXAMINER

Art Unit 1615